OFFICE OF SPECIAL MASTERS
No. 99-329V
September 18, 2006

MONIQUE KANADANIAN,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed
	*	either the next day or four months
SECRETARY OF THE DEPARTMENT OF	*	later by GBS variant within three
HEALTH AND HUMAN SERVICES,	*	weeks of a viral illness; causation?
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petitioner on May 21, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine in January 1995, followed by pain in her heels within a week, and on February 25, 1995, followed by pain in her arms within 24 hours. Petition, ¶ 2 (this is the second paragraph 2). Over the next two

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

months, she had fatigue and heel pain, and was eventually diagnosed with a variant of Guillain-Barré Syndrome (GBS) consisting of small-fiber neuropathy.

According to petitioner's petition, she received her first hepatitis B vaccination on January 28, 1995. The next day, she woke to severe pain in both her heels. After one week, the symptoms disappeared. P. Ex. 11, p. 1. On the day after her second vaccination in February 1995, she had pain in her arms from her shoulders to her hands, which lasted 48 hours. P. Ex. 11, p. 2. She states that, throughout March and April, she had several episodes which lasted 48 hours and then disappeared. *Id.* In June 1995, petitioner started a new job and her heel pain returned, spreading to her toes and ankles. *Id.*

Petitioner is ORDERED TO SHOW CAUSE by **October 27**, **2006** why this case should not be dismissed.

FACTS

Petitioner was born on November 25, 1961.

On September 29, 1982, petitioner saw Dr. Robert G. Feldman, a neurologist, on referral from her neurologist Dr. Herbert Bernstein for a second opinion. Med. recs. at Ex. 29, p. 2. Petitioner had been unsteady, heavy-headed, nauseated, and "drugged" since beginning Tegretol, which was reasonable because the drug is very potent. She began with 200 mg. three times daily. This was discontinued since the prior evening. Before that, she had been on Dilantin 300 mg. daily until September 3rd or 5th. *Id.* This was started in August when she was diagnosed with headaches. An EEG was interpreted in August as abnormal. A definite diagnosis of epilepsy, seizure equivalent, or migraine was never made. Review of the reports of August 24, 1982 and the description of the EEG was compatible with a drowsy and sleeping record of a person of

petitioner's age. Dr. Feldman did not consider it abnormal. An EEG done on April 23, 1976 was also normal. This EEG was also done because of the diagnosis of headache associated with some other systemic illness. Petitioner had not had headaches regularly until the summer. During the summer, she began to have a dull ache almost daily. It was not pounding or associated with nausea, vomiting, or flashing lights. She did not have any other neurological symptoms except for distractibility, poor concentration, and light-headedness. *Id.* She felt she was short of breath. She described some tingling over the right temporomandibular area and over the temporalis muscle. The tenderness was under the scalp on the right side of her head more than on the left, but it occurred bilaterally. A CT scan done at Cardinal Cushing Hospital in early September was normal, but Dr. Feldman wanted to see the pictures. Petitioner's past history included periodic abdominal pain . There was a family history of Mediterranean fever. *Id.*

Hypoglycemia was diagnosed with a blood sugar as low as 38. Med. recs. at Ex. 29, pp. 2-3. Symptoms of cold and clammy agitation common during the summer did not recur while petitioner was in school. Med. recs. at Ex. 29, p. 3. The headaches occurred mostly in the evening around 7:00 p.m. about one and one-half to two hours after she ate supper. The dull ache persisted. *Id.*

Petitioner's bite was a little bit off to the side when she opened her mouth. There was some crepitus at the temporomandibular joint bilaterally, but more laxity and mobility on the right as compared to the left. After opening her jaw and putting pressure in the joints, she reproduced the discomfort she had when she had a headache. *Id.*

On January 24, 1991, petitioner went to the Cambridge Hospital with panic attacks. She had an increase in acute anxiety. She had the same attacks three years previously. She had an

increase in palpitations, stomach pain, diffuse concentration, and an increase in dread. Med. recs. at Ex. 21, p. 76.

On March 8, 1994, petitioner went to the Cambridge Hospital because she had thoughts of killing herself. Med. recs. at Ex. 21, p. 54. She was referred by Dr. Barnes. She reported feeling suicidal for one month, making plans to overdose on heroin with an IV overdose. She reported having heroin at home and a needle to use. She denied ever having hurt herself in the past. She had been "getting ready for this" for a month, cleaning out her closets and cleaning up her computer files. *Id.*

Petitioner was not in treatment at present. She discontinued medications and therapy in December 1993, reportedly at the urging of her husband. She had seen a therapist from May to December 1993 named Virginia Youngren at MacLean. She was on Prozac, Depakote, Trilator, Augmentin, and Xanax. She was on Depakote for a positive EEG which she reported disagreeing with because of no history of seizures. She felt she was overmedicated and the medicines did not help. She spoke with Dr. Barnes about getting a new therapist. She was last hospitalized in December 1993, precipitated by the news that her partner had a terminal illness. The diagnosis was to rule out major depression. *Id.*

Petitioner reported family problems, but would not elaborate. Her mother had a history of depression and her mother's father committed suicide. Med. recs. at Ex. 21, p. 55. Petitioner was employed as a psychiatric nurse at a hospital per diem. She had been married for two years to a gay man. She was a lesbian who had not been seeing a female partner since October. The hospital notes describe petitioner as a 32-year-old lesbian who was casually dressed with adequate hygiene who was guarded and initially slow to engage. Her mood was depressed and

her affect constricted. She had planned to commit suicide by overdosing on heroin but denied having a specific time or date to do it. She denied psychotic symptoms. She had audiovisual hallucinations and paranoid ideation. She had flight of ideas and looseness of associations. *Id.* Her insight and judgment were poor. She was hopeless, stating, "I don't think I can be helped." The doctor's opinion was that she was commitable. The plan was section 12 to Waltham Westan for admission, treatment, and medication. Dr. Barnes was aware of this and would be in contact. Petitioner was not happy about the hospital admission and starting rocking and shaking when she found out. *Id.*

On March 15, 1994, petitioner saw Dr. Monika M. Eisenbud, a psychiatrist, for depression. Med. recs. at Ex. 23, p. 10. Petitioner had been hospitalized several times for depression. *Id.*

On March 21, 1994, petitioner saw Dr. Eisenbud again. Med. recs. at Ex. 23, p. 14. She had some depression as an adolescent. Med. recs. at Ex. 23, p. 15. She had difficulties with her therapist and was sent to a hospital for one week. Med. recs. at Ex. 23, p. 16. Petitioner filled out a questionnaire for Dr. Eisenbud on March 21, 1994. Med. recs. at Ex. 23, p. 118. She stated she had a chronic medical problem of back injury. Med. recs. at Ex. 23, p. 119. She had a psychiatric hospitalization in March 1994 for depression. *Id.*

On March 28, 1994, petitioner saw Dr. Eisenbud again. She looked depressed but was able to go to work. She felt down and her chest hurt as if it were hard to breathe. Med. recs. at Ex. 23, p. 11. On March 28, 1994, Dr. Eisenbud filled out a psychiatric/substance abuse outpatient treatment authorization request. Med. recs. at Ex. 23, p. 123. Petitioner had major depression, recurrent, severe, and in remission. *Id.* She had been severely depressed, acutely

suicidal with a plan with multiple psychiatric hospitalizations during the prior year. She developed repressive transference relationships with past therapies. She had some dissociative episodes, including physically destructive episodes, in therapists' waiting rooms. *Id.* Petitioner had several years of psychotherapy, particularly in the prior two years, some of it intensive. *Id.* Her present functioning was much improved. She was able to work and planning to resume studies. *Id.* Dr. Eisenbud hoped to keep petitioner that way, but there might be recurrent decompensation. *Id.* Petitioner had a mild case of post-traumatic stress disorder following a relationship that in effect was victimizing. Med. recs. at Ex. 23, p. 124. The target symptoms to be addressed were that she remained steeped in recollection and had emotion cathecting in that situation. *Id.*

On April 6, 1994, petitioner saw Dr. Eisenbud again. Increasing her dose of Zoloft helped. Med. recs. at Ex. 23, p. 18.

On April 19, 1994, petitioner saw Dr. Eisenbud again. She felt less depressed and mentally better. Med. recs. at Ex. 23, p. 13.

On May 2, 1994, petitioner saw Dr. Eisenbud again. She wanted to know if the prescriptions were making her sick. Past therapy did not serve her well. She was diagnosed with a dissociative disorder. Med. recs. at Ex. 23, p. 21. She wanted to come monthly. *Id.*

On May 14, 1994, Dr. Eisenbud wrote a letter to Dr. Barnes, stating petitioner was continuing to do well. With petitioner's recent turbulent history, she might experience changing needs. Med. recs. at Ex. 23, p. 22.

On May 31, 1994, petitioner saw Dr. Eisenbud. She was doing well. She was still socially awkward in lesbian circles and came out April 28th. She was on Xanax. Med. recs. at Ex. 23, p. 23.

On July 5, 1994, petitioner saw Dr. Eisenbud. She was stressed out. Dr. Eisenbud increased her Zoloft. Med. recs. at Ex. 23, p. 24. Petitioner saw Dr. Eisenbud on September 20, 1994, September 27, 1994, October 11, 1994, October 19, 1994, October 25, 1994 (discussing the issue of anxiety), and December 27, 1994. Med. recs. at Ex. 23, pp. 25-30.

On January 27, 1995, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 24, p. 3. There is no record of her February 1995 vaccination although it was standard protocol to administer the second vaccination one month after the first. *Id.*

On June 28, 1995, petitioner saw Dr. Hilary Worthen at Cambridge Family Health. Med. recs. at Ex. 3, p. 13. She came in urgently that evening because of foot pain. She started a new job two and one-half weeks previously and had been having increasing pain in both feet. The pain was not bad in the morning, but as she stood all day, her feet became increasingly sore, until she was in agony at the end of the day. The pain started at the heel pad and extended along the lateral margin under the fourth and fifth metatarsals and then across the ball of the foot. When the pain was really bad, it seemed to develop into numbness and extend to her shins. She had an episode of this four months ago (February 1995), but she changed her shoes and it seemed to resolve. Otherwise, she never had a problem like this. Med. recs. at Ex. 2, p. 5.

On examination, petitioner had marked tenderness under the insertion of the plantar fascia and along the lateral aspect of the pad of the foot and into the metatarsal heads, particularly the left fourth metatarsal head which seemed to have dropped slightly. The x-rays looked

unremarkable although the alignment might be off. The doctor was unsure of the problem but petitioner could have had some plantar fasciitis and there might be a neuroma developing. She needed orthotics, some nonsteroidals, and attention to the mechanics of her feet. The doctor doubted petitioner had a vascular problem. *Id.* Dr. Worthen would try to get her an urgent appointment with a podiatrist on the next day. Med. recs. at Ex. 3, p. 13.

From June 29 to July 18, 1995, petitioner was at Mount Auburn Hospital. Dr. Barnes diagnosed short fiber polyneuropathy with neuropathic pain, probable GBS variant. Med. recs. at Ex 2, p. 138. About four weeks prior to admission, petitioner had a viral illness from which she recovered completely. Two days prior to admission, she developed a burning pain in the sole of one foot. Over the next two days, the pain increased to cover her entire foot, accompanied by a loss of sensation and numbness to her knees. She had no motor weakness and her reflexes were intact. She denied any prior episodes. *Id.*

Her past medical history included a herniated disc with back surgery in the 1980s, severe depression, chronic hospitalizations (with the last hospitalization in 1993), and migraine headaches. *Id.* On examination, she had normal motor strength and tone but sensory examination revealed decreased sensation to pin and light touch in a stocking distribution up to her ankles bilaterally. She had some dysesthesias in her calves. She had normal reflexes. CSF showed a protein of 65. *Id.* Nerve conduction studies of her lower extremities and somatosensory evoked potentials were normal. An MRI of her cervical through lumbosacral spine was also negative. Rheumatoid factor was negative. Med. recs. at Ex. 2, p. 137. Over the next two weeks, petitioner had a gradual progression of her symptoms to include a loss of pinprick and light touch over her entire body, sparing only the inner aspect of her upper arms and

upper thighs, and including her face. She developed severe, burning neuropathic pain in both legs, right greater than left, extending on the right to her right lower quadrant and buttocks. Her reflexes remained brisk. She did not respond to a five-day course of Methylprednisolone IV. She also did not respond to a five-day course of IV immunoglobulin. She was transferred to the neurology unit of St. Elizabeth's Hospital. *Id.*

On July 1, 1995, petitioner had nerve conduction studies which were normal in the lower extremities. These findings excluded a pan-sensory polyneuropathy but not a small-fiber nerve involvement. Med. recs. at Ex. 2, p. 134.

On July 18, 1995, petitioner was transferred to St. Elizabeth's Medical Center. Med. recs. at Ex. 10, p. 1. She was discharged two days later with a diagnosis of acute small-fiber polyneuropathy and intractable pain. *Id.* A neurological fellow's note for Dr. Allan Ropper was that petitioner was previously healthy when three weeks previously, she developed bilateral burning and painful pins and needles on the bottom of both feet that spread up to the ankles over five days. Med. recs. at Ex. 10, p. 5. She had similar symptoms in the feet one month ago that resolved on its own. *Id.*

Another history and physical was taken on July 18, 1995. Petitioner had a three-week history of bilateral decreased sensation and burning pain in both lower legs. She was in her usual state of good health until June 27, 1995 when she developed burning pain in the soles of her feet. Over the next few days, the area of pain and decreased sensation advanced to the level of her knees. She had difficulty walking due to the pain, but denied any leg weakness or dizziness. Med. recs. at Ex. 10, p. 7. She also denied any similar episodes in the past. While hospitalized

at Mount Auburn, her pain and decreased sensation advanced to the groin level and, on occasion, also involved both arms. *Id.*

On July 18, 1995, a nursing progress note states that petitioner was transferred from Mount Auburn Hospital with a chief complaint of bilateral foot pain and difficulty walking. She had no known past medical history. She was very weepy on admission. She ambulated independently from the stretcher to bed. She complained of burning pain in both feet. She was able to lift her legs off the bed. Strength was 4-/5 in the lower extremities and 5/5 in the upper extremities. Med. recs. at Ex. 10, p. 11.

A resident agreed with the nurse's note of two-week history of progressive paresthesias with burning, tingling, and numbness in the feet. *Id.*

On July 19, 1995, Dr. Ropper wrote, on careful examination then, there was a disturbing degree of inconsistency. Petitioner reported sensation was altered in her entire legs, buttocks, and perhaps above on the right side of her abdomen. This was in contrast to July 18, 1995, when petitioner felt pinprick without difficulty in her feet and posterior calves on some occasions, but was analgesic on her anterior lower legs without clear dermatome borders. Med. recs. at Ex. 10. p. 12. On pinprick of her legs, buttocks and low back, she jumped and winced, responding that pinprick was painful beyond normal. On the left lower back up to T8-T10, coolness was not felt well but pinprick was okay. On the anterior trunk (lower abdomen and groin), there were no sensory changes. Vibration and position sense were normal in the toes and feet. She could tell coolness from warmth in her legs. Her abdominal superficial and leg deep tendon reflexes were normal. Sweating was normal. Dr. Ropper wrote, "We cannot easily attribute this to a small fiber neuropathy in view of buttock and truncal symptoms and unusual exam. A myelopathy is

possible but odd syndrome for demyelination." *Id.* Pain was still quite severe and she could not walk. She had had a depression but preferred not to have her psychiatrist involved. She had been recently divorced. *Id.*

On July 19, 1995, petitioner was tested for visual evoked responses, and tibial and median somatosensory evoked responses, all of which were normal. Med. recs. at Ex. 2, pp. 131-32.

On July 19, 1995, petitioner complained of nausea, but was able to eat a full lunch. Med. recs. at Ex. 10, p. 13.

On July 20, 1995, petitioner had an EMG which Drs. Drasko Simovich and Michael Hayes interpreted as normal, showing no electrophysiologic evidence of polyneuropathy, radiculopathy, or plexopathy. Sympathetic skin response was present (normal) in all four extremities. Med. recs. at Ex. 2, p. 129; Ex. 10, p. 38.

On July 20, 1995, petitioner had an MRI of her thoracic spine which showed disc herniation at T3-T4, T5-T6, and T6-T7. Med. recs. at Ex. 10, pp. 47-48.

On July 20, 1995, at 2:00 a.m., petitioner complained that the bed was flipping and a woman was trying to strangle her. Med. recs. at Ex. 10, p. 16. She was reassured and fell asleep for two and one-half hours when she woke again and hallucinated more about a woman strangling her. *Id.*

From July 25 to August 3, 1995, petitioner was at Mount Auburn Hospital for a possible relapse of an acute sensory neuropathy. Med. recs. at Ex. 2, p. 126. In late June 1995, she developed pain and paresthesias in her heels and legs which progressed to severe paresthesias of her lower legs, hands, and arms, and eventually involved decreased pinprick sensation over her

entire body. She had no motor involvement and her reflexes were preserved. She had a CSF protein of 65. An MRI of her entire spinal cord was negative. She had negative evoked sensory potentials and NCS/EMG studies. A five-day course of IVIG did not help. On July 18, 1995, she was transferred to St. Elizabeth Hospital, Dr. Allen Ropper's service, for further evaluation and possible plasmapheresis. A repeat CSF showed protein of 44. All central neurological studies were negative and her symptoms markedly improved. *Id.*

On physical examination, her motor strength was normal, her reflexes were intact, her sensory examination, including pinprick, light touch, and proprioception were within normal limits. *Id.* She had a fluctuating neurological examination with variable hypoesthesia in her legs up to her knees or thighs and sometimes in her arms to her shoulders, sparing her face. Med. recs. at Ex. 2, p. 125. A repeat CSF showed a protein of 38. Rheumatologic screening, including ANA, was negative. *Id.*

From August 3 to 16, 1995, petitioner was at Youville Hospital and Rehabilitation Center. She had initially been admitted to Mount Auburn Hospital in June 1995 with pain and paresthesias of the lower extremities, hands, and her entire body. Lumbar puncture, nerve conduction studies, EMGs, evoked sensory potentials, and MRI were all negative. Med. recs. at Ex. 2, p. 117. She was diagnosed with acute sensory polyneuropathy, variant of GBS. She was transferred to St. Elizabeth's Medical Center on July 18, 1995 and discharged two days later. She went back to Mount Auburn Hospital on July 25, 1995 with opiate withdrawal and hypoadrenal syndrome. Med. recs. at Ex. 2, p. 117.

Petitioner's past history included depression. She was on medication for it until 1993. She had had psychologic follow-up in the past. She had migraine headaches several years ago.

She had low back pain secondary to disc disease at L4-L5 in 1984. *Id.* On examination, she had no focal neurologic deficit. She was divorced in March 1995. Med. recs. at Ex. 2, p. 116.

On September 8, 1995, petitioner saw Dr. Henrietta N. Barnes at Cambridge Family Health for follow-up for acute sensory polyneuropathy. Med. recs. at Ex. 2, p. 7. Petitioner could not walk around the block with exhaustion and continued to have some pain in her feet, and occasional tingling and numbness of her legs and occasionally her arms. Some days, she said she felt quite well whereas, on other days, she had more sensory problems. Occasionally, she had nausea and malaise. *Id.* Her examination revealed no motor findings. She had slight decrease in pinprick in her feet, but otherwise pinprick was intact. Her reflexes were 2+ and symmetrical. Dr. Barnes' impression was that she was doing very well and gradually recuperating from sensory polyneuropathy. *Id.*

On October 5, 1995, Dr. Allan H. Ropper, Chief of the Department of Neurology at St. Elizabeth's Medical Center, wrote to Dr. Robin Barnes that he had seen petitioner again for her persistent pain. On examination, her reflexes were all quite brisk but not pathologic. Her sensory examination was "rather curious in that she reports the pin prick as dull all over the body, including the distal extremities. She easily distinguishes between sharp and dull and between several degrees of thermal difference on two sides of a tuning fork." Med. recs. at Ex. 39, p. 3. Joint position sense was quite normal. *Id.* To Dr. Ropper, there was "a premium on determining the genuineness of her symptoms and their relationship to a small fiber sensory neuropathy." Med. recs. at Ex. 39, p. 2. He was inclined to take petitioner's complaints at face value and acknowledge that conventional EMG tests and the like are insensitive to small fiber dysfunction. She might have perineuritis, an inflammatory disorder of the small sensory nerves in the skin. *Id.*

On October 13, 1995, petitioner saw Dr. Barnes with significant increase in her neuropathic pain in her legs up to her thighs over the past week. Med. recs. at Ex. 2, p. 10. She had such burning discomfort that she was barely able to walk around her apartment, even with crutches. She also noted some pain in her hands. She denied localized weakness. *Id.* She had a mild sore throat over the last several days. On examination, she looked depressed and in moderate discomfort. Her feet and legs were uncomfortable to touch. She had decreased pinprick over the entire leg as well as her arms, back, and chest. *Id.*

From October 19 to October 21, 1995, petitioner was in Mount Auburn Hospital for severe neuropathic pain, according to Dr. Barnes. Med. recs. at Ex. 33. p. 268. Dr. Wasserman said there was no additional neurologic diagnosis to explain petitioner's symptoms. On examination, petitioner had dysesthesias and decreased pin sensation in her feet, legs, and lower arms, sparing her inner upper arms, face, and anterior trunk. *Id.*

On January 24, 1996, petitioner saw Dr. Margaret A. Caudill for a behavioral medicine pain program consultation at Deaconess Hospital. Med. recs. at Ex. 22, p. 8. She stated that she had a six-week episode of a viral illness. She was checked for mononucleosis and other problems by her employer, an occupational health group, and nothing showed up. She then switched jobs and received two hepatitis B vaccinations when, one morning, she woke with burning in her feet. After about five to six days, she could hardly walk because of the pain. A podiatrist examined her and found nothing wrong. Over days to weeks, her pain ascended her legs and eventually developed into burning, throbbing, and aching increasing in her upper and lower extremities (primarily the latter), and her trunk, ending at the neck. *Id.* She felt she had respiratory compromise, but this was not documented by pulmonary function testing. She was

tachycardic, short of breath, and hardly able to sit up. *Id.* She separated from her husband in September 1994 and divorced in March 1995. Med. recs. at Ex. 22, p. 9. She was hospitalized in 1993 for reactive depression. *Id.*

On January 30, 1996, petitioner had a brain MRI which was normal, without evidence of demyelinating disease. Med. recs. at Ex. 2, p. 102.

On January 30, 1996, petitioner had an MRI of her cervical spine which showed no evidence of cervical spinal cord demyelinating lesions. Med. recs. at Ex. 2, p. 103.

On May 21, 1996, petitioner saw Dr. Paul B. Lesser, a gastroenterologist, for persistent nausea. Med. recs. at Ex. 28, p. 144. Dr. Lesser diagnosed her nausea as related to her narcotics. *Id.*

On August 28, 1996, petitioner saw Dr. Andrea J. Wagner, Medical Director of Physical Medicine and Rehabilitation at Somerville Hospital. Her problems began June 1995 with pain in her feet, especially in her heels. Med. recs. at Ex. 2, p. 145. On examination her voluntary motor strength was 5/5 in upper and lower extremities. Med. recs. at Ex. 2, p. 144. Deep tendon reflexes were +2 and symmetrical. Sensation to pinprick was decreased distally in upper and lower extremities. Proprioception was intact in both lower extremities. There was no muscle atrophy. Cerebellar testing heel to shin was intact bilaterally. Straight leg raising was asymptomatic. Light palpation of the skin on the plantar surface of the feet increased petitioner's pain. Dr. Wagner diagnosed a chronic pain problem and recommended pain management with tricyclic anti-depressant as well as a psychiatric consultation. *Id.*

On September 25, 1996, petitioner saw Dr. Francis X.J. Bohdiewicz for a physical medicine and rehabilitation evaluation. Med. recs. at Ex. 2, p. 154. She was currently on Social

Security Disability. Med. recs. at Ex. 2, p. 153. On examination, she had functional active range of motion throughout all major joints. Light touch sensation was essentially absent over the lateral aspect of the lower extremity including the feet, with sparing of light touch sensation along the inner aspects of the lower extremities. She had normal tone. Strength in the upper extremities was generally 4-/5 throughout, and in the lower extremities, generally 4 to 4+/5 throughout without any focal or lateralizing weakness. *Id.* Deep tendon reflexes were 2+ and equal bilaterally throughout. Cerebellar testing revealed intact finger to nose bilaterally. *Id.*

Dr. Bohdiewicz's impression was chronic pain with ascending sensory neuropathy, including absent or severely impaired light touch sensation over the lateral aspects of bilateral lower extremities and over the entire surface of both feet. Med. recs. at Ex. 2, p. 152. She was appropriate for an electric/motorized mobility device. Bilateral ankle foot orthoses could help her ambulate. *Id.*

On October 16, 1996, petitioner saw Dr. Janice Wiesman. Med. recs. at Ex. 29, p. 13. On examination, petitioner's deep tendon reflexes were 2/4 and symmetrical. Motor examination in the lower extremities was normal. Sensory examination to cold, vibration, and joint position sense in the lower extremities was normal. Left median and peroneal motor nerve conduction studies with F response were normal. Left median, ulnar, and superficial peroneal sensory responses were normal. Concentric needle EMG of the left upper and lower extremities was normal. Motor unit potentials were of normal morphology and recruited normally. Dr. Weisman did not note any abnormal spontaneous activity. Her impression was that petitioner had a normal study. There was no evidence of a muscle, nerve, plexus, or root lesion. *Id.*

On October 30, 1996, petitioner saw Dr. James A.D. Otis. Med. recs. at Ex. 2, p. 161. Petitioner was in her usual state of health until approximately the beginning of March 1995 (this is the first time petitioner has not said June 1995) when she developed a viral illness. She recovered completely but, about three weeks later, she developed a burning pain on the sole of one foot. Over the next few days, the pain increased to cover the entire foot and was accompanied by a loss of sensation and numbness to both knees. There was no motor weakness. *Id.*

Petitioner said that she had burning pain affecting both lower extremities and both hands which was considerably worse at the bottom of her feet. She characterized it as continuous 10/10 range pain, increased with walking and standing, but, interestingly, not with contact with clothes or water. Med. recs. at Ex. 2, p. 160. On examination, she had motor strength of 5/5 in the upper extremities and, when pain was accounted for, 5/5 in the lower extremities. Med. recs. at Ex. 2, p. 159. Sensory examination showed decrease to vibratory sensation below the knees bilaterally and in the hands bilaterally. Reflexes were 1+ in the upper extremities and 2+ in the lower extremities. EMG was normal, suggesting this was perhaps a small-fiber neuropathy. *Id.*

On April 24, 1997, petitioner saw Peter A. Mosbach, Ph.D., who is a clinical psychologist. Med. recs. at Ex. 2, p. 203. Petitioner's mother has a history of fibromyalgia. *Id.* Petitioner's responses to MMPI-2 suggested that she would experience an increase in her perceived pain when faced with stressful life events. Med. recs. at Ex. 2, p. 202. Her responses also suggested that she had a moderate level of depression. *Id.* She was seeing a psychiatrist weekly. Med. recs. at Ex. 2, p. 201.

On January 13, 1998, Dr. Barnes filled out a payment voucher form for the Massachusetts Rehabilitation Commission. Med. recs. at Ex. 2, p. 238. She first examined petitioner in January 1991. Med. recs. at Ex. 2, p. 237. The date of petitioner's first sign of illness was in June 1995. *Id.*

On April 9, 1998, Dr. Nathaniel P. Katz of the Pain Management Center of Harvard Medical School wrote to Dr. Barnes. Med. recs. at Ex. 2, p. 250. Petitioner's symptoms began rather suddenly in June 1995 with pain and paresthesias that began in her feet and ascended over approximately two weeks into her groin. After about one month, the pain was in her arms as well. The pain was quite severe. Examination showed diffuse loss of pinprick and temperature sensation with preservation of strength and reflexes. All her electrophysiologic studies were negative, including nerve conduction studies and evoked responses. *Id.* Quantitative sensory testing was also negative. *Id.*

Dr. Katz's impression was that petitioner had a small-fiber, painful, peripheral polyneuropathy. Med. recs. at Ex. 2, p. 249. The diagnostic tests primarily assess large-fiber function. Dr. Katz's impression was that there was some amplification by psychological factors, but not a lot. *Id.*

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen

v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had small-fiber neuropathy or GBS variant, but also that the vaccine was a substantial factor in bringing about her small-fiber neuropathy or GBS variant. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case. The onset interval after hepatitis B vaccination was three weeks. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a

vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

In the instant action, petitioner alleges that she had heel pain within 24 hours of her first hepatitis B vaccination, which disappeared after 48 hours, and arm pain within 24 hours of her second hepatitis B vaccination, which disappeared after 48 hours. She also alleges that over the next four months, she had intermittent episodes of pain. The contemporaneous medical records support only that she had heel pain in February which went away when she switched shoes. The pain in January, the arm pain in February, and intermittent episodes of pain over the next four months are not anywhere in the medical records. Petitioner denied in June 1995 that she had experienced in her past anything similar to what brought her to the hospital at that point, other than the transitory pain in February 1995 that disappeared when she changed shoes..

Petitioner gave a history of chronic hospitalization when she was hospitalized in 1995, with the most recent hospitalization in 1993. If petitioner intends to proceed with this case, petitioner shall file all hospitalizations that preceded 1995.

Petitioner shall file a VAERS form with the court if she previously filled one out and sent it (Ex. 8 consists of VAERS information).

In addition, if petitioner intends to continue to allege that her onset of neurologic symptoms was within one day of both her first and second hepatitis B vaccinations, petitioner shall file an opinion from a neurologic expert that hepatitis B vaccine can and did cause the onset of her GBS variant within one day of each vaccination. In addition, the medical expert shall deal with the alternate cause for petitioner's small-fiber neuropathy or GBS variant, which is the viral

illness she had within three weeks of the onset of her burning foot which brought her to Mount Auburn Hospital in June 1995. Three weeks is a medically appropriate time frame within which to find causation.

The undersigned would find it difficult to hold that a hepatitis B vaccination four and five months prior to onset of her neurologic condition was a substantial factor in causing it rather than a viral illness three weeks before onset. This assumes, of course, that petitioner's painful feet in February (as noted in the contemporaneous medical records) that were cured by a change of footwear was not the onset of her neurologic condition. It is unclear to the undersigned that small-fiber neuropathy can come and go in 48 hours over a period of four months. It is also unclear to the undersigned whether small-fiber neuropathy is a demyelinating disease since no medical test (nerve conduction study, EMG, MRI) has ever resulted in a diagnosis that petitioner has a demyelinating illness.

The undersigned notes that Dr. Allan Ropper, an expert in GBS, found in examining petitioner on July 18 and 19, 1995 that she had inconsistency in her symptoms that made diagnosing a small-fiber neuropathy difficult, and her presentation was odd for a demyelinating disease. However, in subsequent writings, he was willing to take petitioner's assertions of pain at face value and diagnose a small-fiber neuropathy.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **October 27, 2006**.

IT IS SO ORDERED.

September 18, 2006
DATE

s/ Laura D. Millman
Laura D. Millman
Special Master